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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,695	04/12/2001	Michael F. Weiser	B0410/7277	7619
22832	7590	11/04/2004	EXAMINER	
KIRKPATRICK & LOCKHART LLP			HAMILTON, LALITA M	
75 STATE STREET			ART UNIT	
BOSTON, MA 02109-1808			PAPER NUMBER	

3624

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,695

Applicant(s)

WEISER ET AL.

Examiner

Lalita M Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on amendment filed on July 22, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7,9 and 11-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7,9 and 11-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10262004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

On January 20, 2004, an Office Action was sent to the Applicant rejecting claims 2-7,9, and 11-51. On July 22, 2004, the Applicant responded by amending claims 3-4, 11, and 50 and canceling claim 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 49 is rejected under 35 U.S.C. 102(a) as being anticipated by Hussein, as set forth in the previous Office Action mailed on January 20, 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7, 9, 13-15, 18-24, 30-37, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss in view of Hussein and Barnhart.

With regard to the amendment to claims 3-4 and 50, Hussein discloses a myocardial tissue implant (see abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an implant device for implantation into myocardial tissue, as taught by Hussein, into the invention disclosed by Neuss and taught by Barnhart, to provide an implant device that resists migration for use in other areas of the body.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss in view of Hussein.

With regard to the amendment to claim 11, Hussein discloses a myocardial tissue implant (see abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an implant device for implantation into myocardial tissue, as taught by Hussein, into the invention disclosed by Neuss, to provide an implant device that resists migration for use in other areas of the body.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss, Hussein, and Barnhart applied to claim 13 above, and in further view of Cottenenceau.

Neuss discloses and Hussein and Barnhart teach the invention substantially as claimed; however, none of the references disclose nor teach varying flexibility is created

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by varying the distance between individual coils of the helical spring or the helical spring being formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring. Cottenceau teaches a spiral device having varying flexibility is created by varying the distance between individual coils of the helical spring and the helical spring being formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring (fig.13-14 and col.5, lines 25-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate varying flexibility is created by varying the distance between individual coils of the helical spring and the helical spring being formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring, as taught by Cottenceau into the device disclosed by Neuss and taught by Hussein and Barnhart, to help prevent migration of the device when it is in place.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss, Hussein, and Barnhart as applied to claim 22 above, and in further view of Whalen.

Neuss discloses and Hussein and Barnhart teaches the invention substantially as claimed; however, neither reference discloses nor teaches a tail that includes a proximal end that is secured to the broadly wound coil, the proximal end joined to the broad loop by being wrapped about the loop, or the proximal end joined to the broad loop coil by welding or a malleable sleeve. Whalen teaches a flexible helical spring (col. 1, lines 48-53) comprising a helically wound coil having a proximal end secured to the broadly

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wound coil (fig.2: 30 and 34), the proximal end joined to the broad loop coil by being wrapped around the loop (fig.2), and welding as a means of securing (col.2, lines 40-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a tail that includes a proximal end that is secured to the broadly wound coil and the proximal end joined to the broad loop by being wrapped about the loop, as taught by Whalen into the device disclosed by Neuss and taught by Hussein and Barnhart, in order to provide a means of maintaining the coils in a circular shape; it would have been obvious to one having ordinary skill in the art at the time the invention was made to join the proximal end to the broad loop coil either by welding or a malleable sleeve as alternative means of securing.

Claims 38-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein in view of Neuss, as set forth in the previous Office Action mailed on January 20, 2004.

Response to Arguments

Applicant's arguments filed July 22, 2004 have been fully considered but they are not persuasive. The Applicant argues that Neuss does not disclose nor teach a myocardial implant having a tail, surgical adhesive applied to the device, or coils of the distal portion defining a constant diameter. In response, due to the amendment to the claims, the Examiner has incorporated Hussein as a teaching of a myocardial implant configured to resist migration that may be implanted into the tissue. Neuss discloses an implant having configuration that may resist migration, and both Barnhart and Hussein teach implants having similar structural designs as that of Neuss. The Examiner found

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it to have been obvious to one having ordinary skill in the art at the time the invention was made to modify the structure of the implant disclosed by Neuss to include a tail and to be configured for use in myocardial tissue, since the structural designs of the implants are similar.

With regard to Barnhart, the Applicant argues that Barnhart does not disclose a device having a tail defining a profile that is larger than the distal portion of the body. In response, the Examiner has incorporated Barhart as a teaching of a spiral configuration having a tail at the end. The Examiner found it obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Neuss to provide a tail at the end to help prevent migration upon implantation.

The Applicant argues that neither Neuss nor Barhart could be configured to resist migration in the myocardium. In response to this addition to the claims, the Examiner has incorporate Hussein, which teaches an implantable device having a similar configuration as the devices disclosed by Neuss and taught by Barnhart. The device taught by Hussein is configured to resist migration in the myocardium.

With regard to the Cottonceau reference, the Applicant argues that the reference is irrelevant. In response, Cottonceau teaches a device having a spiral configuration that is similar to the devices disclosed by Neuss and taught by Barnhart and Hussein. The Examiner thus contends that Cottonceau is relevant in that he teaches that a device having a spiral configuration with varying flexibility along the length of the spring is known.

With regard to the Whalen reference, the Applicant argues that there is no

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motivation to combine Whalen with any of the other references. In response, Whalen discloses a device having a spiral configuration that the Examiner found to be similar to the spiral configurations disclosed and taught by the other references. Whalen taught that the end of the wire being joined to a coil by welding or a malleable sleeve was a known feature; therefore, the Examiner found motivation to combine Whalen with the other references to demonstrate that an alternative means of securing was well known and practiced.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

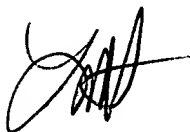
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin can be reached on (703) 308-1065. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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